



P.B.5818 - Patentlaan 2
2280 HV Rijswijk (ZH)
☎ +31 70 340 2040
TX 31651 epo nl
FAX +31 70 340 3016

Europäisches
Patentamt

Zweigstelle
in Den Haag
Recherchen-
abteilung

European
Patent Office

Branch at
The Hague
Search
division

Office européen
des brevets

Département à
La Haye
Division de la
recherche

Sgarbi, Renato
Ing. A. Giambrocono & C. S.r.l.
Via Rosolino Pilo 19/B
20129 Milano
ITALIE

PIC. 1 5 GEN 2004

Sgarbi

Datum/Date

15.01.04

Zeichen/Ref./Réf.

G68932/RS/sgb

Anmeldung Nr./Application No./Demande n°/Patent Nr./Patent No./Brevet n°.

03016306.7-2405-

Anmelder/Applicant/Demandeur/Patentinhaber/Propriétaire/Titulaire

Vicuron Pharmaceuticals, Inc.

COMMUNICATION

The European Patent Office herewith transmits as an enclosure the European search report for the above-mentioned European patent application.

If applicable, copies of the documents cited in the European search report are attached.

☐ Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.

The following specifications given by the applicant have been approved by the Search Division:

☒ abstract

☒ title

☐ The abstract was modified by the Search Division and the definitive text is attached to this communication.

The following figure will be published together with the abstract:

4

REFUND OF THE SEARCH FEE

If applicable under Article 10 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.





DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.CI.7)
X	US 6 551 591 B1 (LEE MAY D) 22 April 2003 (2003-04-22)	1-21	C07K14/195 C07K2/00
Y	* the whole document *	1-21	C07K4/04 C12P1/06
Y	EP 0 592 835 A (SQUIBB BRISTOL MYERS CO) 20 April 1994 (1994-04-20) * the whole document *	1-21	A61K38/02 A61P31/04 A23K1/17 /(C12P1/06, C12R1:01)
Y	HAYAKAWA M ET AL: "Distribution of antibiotic-producing Microbispora strains in soils with different pHs" ACTINOMYCETES, vol. 6, no. 3, 1995, pages 75-79, XP008025139 * abstract *	1-21	
Y	XU S-Z ET AL: "Isolation of the genus Microbispora from soil of China" WEISHENGWU XUEBAO, vol. 19, no. 3, 1979, pages 255-258, XP008025262 ISSN: 0001-6209 * abstract *	1-21	
Y	LAZZARINI A ET AL: "Rare genera of actinomycetes as potential producers of new antibiotics." ANTONIE VAN LEEUWENHOEK, vol. 78, no. 3-4, December 2000 (2000-12), pages 399-405, XP008025144 ISSN: 0003-6072 * abstract * * figure 3 *	1-21	
The present search report has been drawn up for all claims			TECHNICAL FIELDS SEARCHED (Int.CI.7)
			C07K C12P C12R A61K A23K
Place of search		Date of completion of the search	Examiner
THE HAGUE		23 December 2003	van de Kamp, M
CATEGORY OF CITED DOCUMENTS			
X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document		T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons &: member of the same patent family, corresponding document	

7

EPO FORM 1503 03.02 (P04C01)



DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.CI.7)
A	DATABASE WPI Section Ch, Week 198451 Derwent Publications Ltd., London, GB; Class B04, AN 1984-316058 XP002263383 -& JP 59 198982 A (MEIJI SEIKA KAISHA), 10 November 1984 (1984-11-10) * abstract *		
D,A	--- MCAULIFFE O ET AL: "Lantibiotics: Structure, biosynthesis and mode of action" FEMS MICROBIOLOGY REVIEWS, vol. 25, no. 3, May 2001 (2001-05), pages 285-308, XP002209342 ISSN: 0168-6445 * the whole document *		
D,A	--- SAHL H-G ET AL: "Lantibiotics: biosynthesis and biological activities of uniquely modified peptides from Gram-positive bacteria" ANNUAL REVIEW OF MICROBIOLOGY, vol. 52, 1998, pages 41-79, XP001098220 ISSN: 0066-4227 * the whole document *		TECHNICAL FIELDS SEARCHED (Int.CI.7)
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 23 December 2003	Examiner van de Kamp, M
CATEGORY OF CITED DOCUMENTS X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document		T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons ----- &: member of the same patent family, corresponding document	

7

EPO FORM 1503 03.02 (P04C01)



This application is covered by the extended European search report pilot project at present running within the European Patent Office, applied to all European patent applications filed as first filing and searched on or after 01.07.03. Under this project the EPO issues together with the search report an opinion on whether the application and the invention to which it relates meet the requirements of the EPC. This non-binding opinion is issued free of charge as a service. This opinion may be used as the basis for an informed decision as to whether it is desired to pursue the application further or not.

For further details of this pilot project, the applicant's attention is directed to the Official Journal edition 5/2003. If any further immediate questions or comments arise the EPO Customer Services: +31-70-340 4500 or +49-89-2399 2828 can be contacted.

The attached opinion reveals that the application or the invention to which it relates appear not to meet the requirements of the Convention (see comments on enclosed Form 2906).

If the applicant wishes to continue with this application the examination fee must be paid. Where appropriate amendments can be filed to address the objections raised in the opinion, thus shortening the overall procedure. If no amendments are filed, the opinion will be re-issued as the first official communication under Article 96(2) and Rule 51(2) EPC.

If the examination fee has already been paid and the right to the communication under Article 96(1) EPC has been waived for this application, the first official communication under Article 96(2) and Rule 51(2) EPC will be issued promptly.



The examination is being carried out on the **following application documents**:

Text for the Contracting States:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LU MC NL PT RO SE SI SK TR LI

Description, pages:

1-40 as originally filed

Claims, No.:

1-21 as originally filed

Drawings, sheets:

1/14-14/14 as originally filed

1 Documents

The following document is referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: US-B1-6 551 591 (LEE MAY D) 22 April 2003

D2: EP-A-0 592 835 (SQUIBB BRISTOL MYERS CO) 20 April 1994

D3: HAYAKAWA M ET AL: 'Distribution of antibiotic-producing Microbispora strains in soils with different pHs', ACTINOMYCETES, vol. 6, no. 3, 1995, pages 75-79

D4: XU S-Z ET AL: 'Isolation of the genus Microbispora from soil of China', WEISHENGWU XUEBAO, vol. 19, no. 3, 1979, pages 255-258

D5: LAZZARINI A ET AL: 'Rare genera of actinomycetes as potential producers of new antibiotics.' ANTONIE VAN LEEUWENHOEK, vol. 78, no. 3-4, December 2000, pages 399-405



2 Article 54 EPC - Novelty

2.1 Objection to novelty - claims 1-3

The present application does not meet the requirements of Art. 52(1) EPC, because the subject-matter of independent **claims 1-3** is not new in the sense of Art. 54(1) and (2) EPC.

D1 discloses lanthionine- and dehydro-residue-containing antibiotics isolated from a *Microbispora* sp. strain, *Microbispora corallino*, arbitrarily denominated MF-BA-1768 (alpha1 and beta1), characterised by physical parameters (molecular weight deduced from mass spectrum, UV spectrum, IR spectrum, ¹³C-NMR spectrum). The parameter values given for antibiotic 107891 and its components (factors A1 and A2) resemble those disclosed for MF-BA-1768 (alpha1 and beta1), and appear indiscriminately identical given the differences in recording conditions and spectral resolution. Hence, in the absence of further proof for the fact that antibiotic 107891 and/or its factors A1 and A2 is/are distinguishable from antibiotic MF-BA-1768 and/or its factors alpha1 and beta1, it is assumed that antibiotic 107891 and/or its factors A1 and A2 is/are identical with antibiotic MF-BA-1768 and/or its factors alpha1 and beta1 as disclosed in **D1**.

2.2 Objection to novelty - claims 4-20

The same reasoning as given under 2.1 is extended to the subject-matter of **claims 4-20**, the fact that 107891 is indiscriminately identical with MF-BA-1768 rendering the subject matter of **claims 4-20** not novel, since **D1** also discloses a process for producing the antibiotic(s) disclosed in it, the process parameters of said process as claimed in current **claims 4-15** being disclosed in **D1**, and since **D1** further discloses pharmaceutical applications of the antibiotic(s) disclosed in it, falling within the terms of current **claims 16-20**.

2.3 Objection to novelty - claim 21

In the absence of proof for the contrary, antibiotic 107891-producing *Microbispora* sp. ATCC PTA-5024, as claimed in **claim 21**, is assumed to be identical with or a variant or mutant of the MF-BA-1768-producing *Microbispora* strain disclosed in **D1**. The *Microbispora* sp. disclosed in **D1** is therefore considered to fall within the terms of **claim 21**.



2.4 Thus, **claims 1-21** lack novelty, contrary to Art. 54(1) EPC.

3 Article 56 EPC - Inventive Step

3.1 *Objection to inventivity*

Even if novel subject-matter could be established, the present application does not meet the requirements of Art. 52(1) EPC because the subject-matter of **claims 1-21** does not involve an inventive step in the sense of Art. 56 EPC.

(a) **D1** and **D2** are independently considered to represent the most relevant state of the art with respect to the inventivity of **claims 1-21**. **D1** and **D2** disclose antibiotics isolated from a *Microbispora sp.* strain, methods of isolation and purification, methods of use, and the producing strains.

(b) The subject-matter of **claims 1-21** differs primarily from **D1** in that a purportedly novel antibiotic and producing strain is claimed, and from **D2** that a distinctly novel antibiotic and producing strain is claimed.

(c) The problem to be solved by the present application may therefore primarily be regarded as providing a further antibiotic, as well as a further producing strain.

(d) The solution as proposed is the antibiotic 107891 as claimed in **claims 1-3**, as well as methods of isolation and purification from a *Microbispora sp.* strain, methods of use, and the producing strain, according to **claims 4-21**.

(e) This solution cannot however be considered as involving an inventive step for the following reason:

- **D3-5** independently disclose that *Microbispora spp.* strains are well-known producers of antibiotics. The person skilled in the art will therefore seriously consider, in order to solve the problem, to further screen *Microbispora spp.* strains in order to isolate a further antibiotic from them, using appropriate isolation,



purification, and characterisation methods falling within the knowledge and ability of the skilled person. In the absence of any special technical effect, the antibiotic 107891 as well as methods for its isolation, purification, characterisation, and use, as well as its producing strain, therefore represent a mere selection from a known reservoir which the skilled person will explore in order to solve the problem posed, thereby rendering the solution non-inventive.

Thus, **claims 1-21** lack inventivity, contrary to Art. 56 EPC

4 Concluding matters

4.1 Request for new claims

It is not at present apparent which part of the application could serve as a basis for a new, allowable claim. Should the applicant nevertheless regard some particular matter as patentable, an independent claim should be filed taking account of Rule 29(1) EPC. Any amendments should comply with Art. 123(2) EPC. The applicant should also indicate in the letter of reply the difference of the subject-matter of the new claim vis-à-vis the state of the art, particularly **D1**, and the significance thereof.

4.2 Identification of amendments

In order to facilitate the examination of the conformity of the amended application with the requirements of Art. 123(2) EPC, the applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based.

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

4.3 New information

Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be



Bescheid/Protokoll (Anlage)

Communication/Minutes (Annex)

Notification/Procès-verbal (Annexe)

Blatt
Sheet
Feuille

5

Anmelde-Nr.:
Application No.: 03 016 306.7
Demande n°:

confined to the letter of reply and not be incorporated into the application (Art. 123(2) EPC and Guidelines, C-VI, 5.7 et seq.).

Mart van de Kamp

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 03 01 6306

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

23-12-2003

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 6551591	B1	22-04-2003	NONE		
EP 0592835	A	20-04-1994	AU	4746593 A	31-03-1994
			CA	2106446 A1	24-03-1994
			EP	0592835 A2	20-04-1994
			JP	6211615 A	02-08-1994
JP 59198982	A	10-11-1984	NONE		